

AMENDMENTS TO THE CLAIMS

1. (Original) a device for placement within a mammal at a position near the stomach for the treatment of obesity, said device comprising:

(a) at least two or more expandable devices; wherein said expandable devices are sized and shaped such that when expanded said expandable devices decrease the volume of the stomach;

(b) at least one or more filling tubes having an inlet and an outlet connected to each of said expandable devices such that fluid can flow through said filling tubes to inflate or deflate said expandable devices;

(c) an access device having an adjusting port connected to each of said filling tubes for deflating and inflating said expandable devices; wherein said access device is sized and shaped such that a tight seal is formed between said adjusting port and said filling tube, and wherein said access device is sized and shaped such that said access device may be placed subcutaneously near the antero-lateral abdominal wall of the mammal; and

wherein:

(d) when a fluid carrier containing fluid is attached to said adjusting port, fluid may be injected or withdrawn from said expandable devices; wherein as fluid is injected into said expandable devices, said expandable devices expand to decrease the volume of the stomach.

2. (Original) A device as recited in Claim 1, wherein said expandable devices are placed at a pregastric location anterior to the stomach body.

3. (Original) A device as recited in Claim 1, wherein said expandable devices are placed at a pregastric location anterolateral to the stomach body.

4. (Original) A device as recited in Claim 1, wherein said expandable devices are placed at a retrogastric location posterior to the stomach.

5. (Original) A device as recited in Claim 1, wherein said expandable devices are placed at a retrogastric location posterolateral to the stomach body.

6. (Original) A device as recited in Claim 1, wherein at least two of said expandable devices are

spherical-shaped.

7. (Original) A device as recited in Claim 1, wherein at least one of said expandable devices is crescent-shaped.

8. (Original) A device as recited in Claim 1, wherein said device additionally comprises a subcutaneous anchor sized and shaped such that said subcutaneous anchor anchors said expandable devices to the antero-lateral abdominal wall of the mammal.

9. (Original) A device as recited in Claim 8, wherein said subcutaneous anchor is a distensible balloon.

10. (Original) A device as recited in Claim 8, wherein said subcutaneous anchor is a ring lock.

11. (Canceled)

12. (Original) A device as recited in Claim 1, wherein said fluid is selected from the group consisting of CO₂, isotonic dextrose, and an isotonic saline.

13. (Original) A device as recited in Claim 1, wherein said fluid carrier is a hypodermic syringe.

14. (Currently Amended) A device as recited in Claim 1, wherein said device additionally comprises one or more intragastric anchors sized and shaped such that said intragastric anchors ~~fixators~~ are inserted into the stomach to bind said ~~gastrie~~ expandable devices against the exterior surface of the stomach body; wherein the number of said intragastric anchors corresponds to the number of said expandable devices.

15. (Currently Amended) A device as recited in Claim 14, wherein said filling tubes additionally comprise at least one intragastric access channel sized and shaped such that exterior and interior portions of the stomach may be accessed by said intragastric anchors.

16. (Original) A device as recited in Claim 14, wherein said intragastric anchors are collapsible, fixation discs.

17. (Original) A method for promoting weight loss in a mammalian using a device as recited in Claim 1; said method comprising inserting the filling tubes containing expandable devices to a predetermined position near the stomach body; partially inflating the expandable devices sequentially with a fluid; withdrawing the filling tubes until each partially inflated gastric expandable device contacts the abdominal wall; inflating the expandable devices to a volume sufficient to compress the body of the stomach; cutting the filling tubes to an appropriate length; attaching the inlets of each filling tube a corresponding adjusting port of the access device; placing the access device at a subcutaneous location near the abdominal wall; and closing the skin with sutures.

18. (Original) A method as recited in Claim 17, wherein said method additionally comprises placing a subcutaneous fixator around the filling tubes at a subcutaneous location near the abdominal wall and inflating the subcutaneous fixator with fluid to anchor the expandable devices and the access device.

19. (Original) A method as recited in Claim 18, wherein the subcutaneous anchor is a distensible balloon.

20. (Original) A method as recited in Claim 18, wherein the subcutaneous anchor is a ring lock.

21. (Original) A method as recited in Claim 17, wherein said method additionally comprises placing one or more intragastric anchors into the stomach to bind the expandable devices against the exterior surface of the stomach body; wherein the number of intragastric anchors corresponds to the number of expandable devices.

22. (Original) A method as recited in Claim 21, wherein the filling tubes additionally comprise at least one intragastric access channel sized and shaped such that exterior and interior portions of the stomach may be accessed by the intragastric anchors.

23. (Original) A method as recited in Claim 17, wherein the expandable devices are placed at a

pregastric location anterior to the stomach body.

24. (Original) A method as recited in Claim 17, wherein the expandable devices are placed at a pregastric location anterolateral to the stomach body.

25. (Original) A method as recited in Claim 17, wherein the expandable devices are placed at a retrogastric location posterior to the stomach.

26. (Original) A method as recited in Claim 17, wherein the expandable devices are placed at a retrogastric location posterolateral to the stomach body.

27. (Original) A method as recited in Claim 17, wherein at least two of the expandable devices are spherical-shaped.

28. (Original) A method as recited in Claim 17, wherein at least one of the expandable devices is crescent-shaped.

29. (Original) A method as recited in Claim 17, wherein the fluid is selected from the group consisting of CO₂, isotonic dextrose, and an isotonic saline.

30. (Original) A method as recited in Claim 17, wherein the fluid carrier is a hypodermic syringe.

31. (New) A device for placement within a mammal at a position near the stomach for treatment of obesity, said device comprising:

at least two expandable portions, wherein said expandable portions are sized and shaped such that when placed adjacent the stomach and expanded, said expandable portions form a barrier to reduce the volume of the stomach;

at least one filling tube having an inlet and an outlet, wherein each said expandable portion is connected to an outlet of at least one of said at least one filling tube so that fluid can flow through said at least one filling tube to inflate or deflate said expandable portions; and

an access device having a adjusting port connected to at least one of said at least one filling tube

for deflating and inflating said expandable portions, wherein a tight seal is formed between said adjusting port and said at least one filling tube, and wherein said access device is sized and shaped such that said access device may be placed subcutaneously.

32. (New) The device of claim 31, comprising at least two filling tubes, wherein one of said at least two filling tubes is connected to a first of said at least two expandable portions, and wherein a second of said at least two filling tubes is connected to a second of said at least two expandable devices.

33. (New) The device of claim 32, wherein said first expandable portion is at least partially inflated with a liquid and said second expandable portion is at least partially inflated with a gas.

34. (New) The device of claim 32, wherein said first expandable portion is inflated with a liquid and said second expandable portion is inflated with a gas.

35. (New) The device of claim 31, wherein at least one of said expandable portions is crescent-shaped.

36. (New) The device of claim 32, wherein said liquid is selected from the group consisting of isotonic dextrose and isotonic saline.

37. (New) The device of claim 33, wherein said liquid is selected from the group consisting of isotonic dextrose and isotonic saline.

38. (New) The device of claim 31, further comprising a subcutaneous anchor sized and shaped such that said subcutaneous anchor anchors said expandable portions to the antero-lateral abdominal wall of the mammal.

39. (New) The device of claim 38, wherein said subcutaneous anchor comprises a balloon.

40. (New) The device of claim 39, wherein said balloon of said subcutaneous anchor is distensible.

41. (New) The device of claim 38, wherein said subcutaneous anchor comprises a ring lock.

42. (New) The device of claim 31, further comprising at least one intragastric anchor sized and shaped such that said intragastric anchors are insertable into the stomach to bind said expandable portions against an exterior surface of the stomach.

43. (New) The device of claim 42, wherein the number of said intragastric anchors in said device equals the number of said expandable portions.

44. (New) The device of claim 42, wherein at least one of said filling tubes comprises at least one intragastric access channel sized and shaped such that exterior and interior portions of the stomach are accessible via said intragastric anchors.

45. (New) The device of claim 42, wherein at least one of said at least one intragastric anchors is collapsible.

46. (New) The device of claim 42, wherein at least one of said at least one intragastric anchors comprises a collapsible fixation disc.

47. (New) The device of claim 46, further comprising an attached suture configured to be pulled when said at least one intragastric anchor is positioned within the stomach and unfolds, thereby forming a snug fit between the exterior surface of the stomach and said expandable portions.

48. (New) The device of claim 42, wherein said at least one intragastric anchor is formed of a biocompatible material capable of shape memory.

49. (New) The device of claim 48, wherein said biocompatible material capable of shape memory comprises a nickel-titanium alloy coated with at least one of polytetrafluoroethylene polyethylene terephthalate, polyethylene and silicone.

50. (New) The device of claim 42, wherein said at least one intragastric anchor is covered with a biocompatible material to help seal a gastric puncture site formed when anchoring said at least one

intra-gastric anchor.

51. (New) The device of claim 50, wherein said biocompatible material is selected from the group consisting of: polytetrafluoroethylene, polyethylene terephthalate, polyethylene and silicone.

52. (New) The device of claim 31, wherein said at least two expandable portions are expandable to form a compressive barrier that reduces the volume of the stomach and minimizes post-implantation movement.

53. (New) The device of claim 52, wherein a shape of said compressive barrier is adjustable, via changing the volume of one or more of said at least two expandable portions, to complement a contour of surrounding tissues and organs.

54. (New) The device of claim 31, wherein said at least two expandable portions are sized and shaped to complement each other such that when expanded, said at least two expandable portions cluster to form a compressive barrier capable of reducing stomach volume and minimizing post-implantation movement.

55. (New) The device of claim 31, wherein at least one of said expandable members comprises polyurethane elastomer.

56. (New) The device of claim 31, wherein said at least one filling tube comprises at least one of polyurethane and Tygon.

57. (New) The device of claim 31, wherein at least one of said at least one filling tubes comprises two channels.

58. (New) A method of treating obesity in a patient, said method comprising:
making a minimally invasive, percutaneous opening to the abdominal cavity of the patient;
passing a device having at least two expandable portions through said opening while the at least two expandable portions are in a contracted configuration;
positioning the expandable portions adjacent the stomach of the patient;

expanding the expandable portions; and
anchoring the device to the abdominal wall of the patient.

59. (New) The method of claim 58, wherein said expanding comprises expanding the expandable portions to a partially expanded configuration prior to said anchoring, and then at least one of the expandable portions is further expanded.

60. (New) The method of claim 58, wherein the expandable portions are expanded sequentially.

61. (New) The method of claim 59, wherein the expandable portions are expanded to the partially expanded configuration sequentially.

62. (New) The method of claim 58, wherein said anchoring comprises placing a subcutaneous anchor within a fatty layer between the skin and abdominal wall or subperitoneal region of the patient.

63. (New) The method of claim 62, wherein at least one filling tube extends from the expandable portions through the abdominal wall, and the subcutaneous anchor is attached to the at least one filling tube.

64. (New) The method of claim 58, wherein the device is passed through the opening via an access sheath inserted in the opening.

65. (New) The method of claim 64, wherein the expandable portions are contained within introducer tubes that are passed through the access sheath.

66. (New) The method of claim 65, wherein the expandable portions are released from the introducer sheaths after said positioning.

67. (New) The method of claim 58, wherein said positioning comprises positioning the expandable portions at a pregastric location.

68. (New) The method of claim 58, wherein said positioning comprises positioning the expandable portions at a retrogastric location.

69. (New) The method of claim 58, further comprising inserting a nasogastric tube into the stomach.

70. (New) The method of claim 59, wherein upon the further expansion of at least one of the expandable portions, a compressive barrier is formed that reduces the volume of the stomach and minimizes post-implantation movement.

71. (New) The method of claim 58, wherein said anchoring comprises expanding a balloon-like device that circumscribes at least one filling tube connected to said expandable portions and protruding out of the abdominal wall.

72. (New) The method of claim 58, wherein said anchoring comprises locking a ring lock around at least one filling tube and against the abdominal wall, said at least one filling tube being connected to said expandable portions and protruding out of the abdominal wall.

73. (New) The method of claim 69, further comprising inflating the stomach through the nasogastric tube to facilitate better visualization under fluoroscopy to determining a proper location for an access site for said making a minimally invasive, percutaneous opening.

74. (New) The method of claim 58, wherein said minimally invasive, percutaneous opening is made by inserting a micropuncture needle through an access site below the rib cage, into the peritoneal cavity immediately in front of the anterior gastric wall.

75. (New) The method of claim 74, further comprising passing a microwire through the microneedle under fluoroscopic guidance, into the peritoneal cavity.

76. (New) The method of claim 75, further comprising removing said microneedle over said microwire and inserting an introducer over said microwire through said percutaneous opening and into the peritoneal cavity.

77. (New) The method of claim 76, further comprising removing the microwire and inserting a guidewire through the introducer.

78. (New) The method of claim 77, further comprising progressively dilating the percutaneous opening with progressively larger dilators.

79. (New) The method of claim 78, further comprising placing a peel-away access sheath through the opening after said progressively dilating.

80. (New) The method of claim 79, further comprising evacuating air from the stomach via a nasogastric tube.

81. (New) The method of claim 80, wherein said passing a device having at least two expandable portions through said opening while the at least two expandable portions are in a contracted configuration comprises inserting said expandable portions connected to at least one filling tube via introducer tubes.

82. (New) The method of claim 81, wherein said expanding comprises partially expanding said expandable portions at locations adjacent the stomach.

83. (New) The method of claim 82, further comprising removing the introducer tubes and pulling said at least one filling tube until the partially expanded expandable portions contact the abdominal wall.

84. (New) The method of claim 83, further comprising removing the peel-away access sheath and anchoring the expandable portions against the abdominal wall by placing an anchor subcutaneously between the skin and the abdominal wall.

85. (New) The method of claim 84, further comprising further expanding at least one of said expandable portions to a volume sufficient to compress the stomach.

86. (New) The method of claim 85, further comprising cutting said at least one filling tube to an appropriate length for attachment to an access member and attaching said at least one filling tube to said access member, and placing said access member within the fatty layer between the skin and the abdominal wall.

87. (New) A method of treating obesity in a patient, said method comprising:
making a minimally invasive, percutaneous opening to the abdominal wall of the patient;
passing a device having at least two expandable portions through said opening while the at least two expandable portions are in a contracted configuration;
positioning the expandable portions in an anatomical compartment, space or layer of the abdominal wall of the patient; and
expanding the expandable portions to apply compressive force to the stomach.

88. (New) A method of treating obesity in a patient, said method comprising:
making a minimally invasive, percutaneous opening to the abdominal cavity of the patient;
sequentially passing at least two expandable portions of a device through said opening, while in a contracted configuration;
positioning the expandable portions adjacent the stomach of the patient;
expanding the expandable portions; and
anchoring the device to the abdominal wall of the patient.

89. (New) The method of claim 88, further comprising anchoring said expandable portions to the stomach.

90. (New) The method of claim 89, wherein said expandable portions are anchored to the stomach prior to anchoring the device to the abdominal wall.

91. (New) The method of claim 89, wherein each expandable member includes a filling tube extending therethrough, each filling tube having two channels, said method further comprising

anchoring at least one of the expandable portions to the stomach by installing an intragastric anchor through one of said channels.

92. (New) The method of claim 91, further comprising puncturing the stomach wall with a needle; injecting contrast medium into the stomach to determine the location of the needle relative to the stomach fluoroscopically; and advancing the intragastric anchor in a collapsed configuration through the needle using a guidewire, wherein the anchor has a suture affixed thereto; wherein upon exiting the needle, the intragastric anchor expands to an expanded configuration that prevents it from being retracted back out of the stomach.

93. (New) The method of claim 92, further comprising removing the needle and inserting the guidewire and suture through one of said channels.

94. (New) The method of claim 92, further comprising removing the guidewire and pulling back on the suture to anchor the intragastric device to the stomach wall.

95. (New) The method of claim 94, further comprising repeating the steps for intragastric anchoring for each remaining expandable portion that has not yet been anchored to the stomach.

96. (New) A device for placement within a mammal at a position near the stomach for treatment of obesity, said device comprising:

at least two space-occupying portions, sized and shaped such that when placed adjacent the stomach in an operable configuration, said portions form a barrier to reduce the volume of the stomach, relative to a volume achievable by the stomach upon expanding when the barrier is not present;

at least one filling tube having an inlet and an outlet, wherein at least one of said portions is expandable and is connected to an outlet of at least one of said at least one filling tube so that fluid can flow through said at least one filling tube to fill or unfill said expandable portion; and

an access device having an adjusting port connected to at least one of said at least one filling tube for filling and unfilling said at least one expandable portion, wherein a tight seal is formed between said adjusting port and said at least one filling tube, and wherein said access device is sized and shaped such that said access device may be placed subcutaneously.

97. (New) The device of claim 96, wherein a shape of said barrier is adjustable, via changing the volume of one or more of said at least two space-occupying portions, to complement a contour of surrounding tissues and organs.

98. (New) The device of claim 96, wherein a first of said portions is at least partially filled with a liquid and a second of said portions contains a gas.

99. (New) The device of claim 96, wherein at least one of said portions is crescent-shaped.

100. (New) The device of claim 96, further comprising a subcutaneous anchor sized and shaped such that said subcutaneous anchor anchors said portions to the abdominal wall of the mammal.

101. (New) The device of claim 100, wherein said subcutaneous anchor comprises a ring lock.

102. (New) The device of claim 96, wherein at least one of said portions comprises polyurethane elastomer.

103. (New) The device of claim 96, wherein said at least one filling tube comprises at least one of polyurethane and Tygon.

104. (New) A method of treating obesity in a patient, said method comprising:
making a minimally invasive, percutaneous opening to the abdominal wall of the patient;
passing a device having at least two portions through said opening;
positioning the expandable portions in an anatomical compartment, space or layer of the abdominal wall of the patient; and
expanding at least one of the portions to form a barrier that inhibits expansion of the stomach.

105. (New) The method of claim 104, further comprising changing a shape of the barrier by increasing or decreasing expansion of at least one of the portions.

106. (New) The method of claim 104, further comprising anchoring the device to the abdominal wall of the patient.